Complete Summary

GUIDELINE TITLE

Best practice policy statement for the prevention of deep vein thrombosis in patients undergoing urologic surgery.

BIBLIOGRAPHIC SOURCE(S)

American Urological Association Education and Research, Inc. Best practice policy statement for the prevention of deep vein thrombosis in patients undergoing urologic surgery. Linthicum (MD): American Urological Association Education and Research, Inc.; 2008. 29 p. [43 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 3, 2008 – Innohep (tinzaparin): The U.S. Food and Drug Administration (FDA) has requested that the labeling for Innohep be revised to better describe overall study results which suggest that, when compared to unfractionated heparin, Innohep increases the risk of death for elderly patients (i.e., 70 years of age and older) with renal insufficiency. Healthcare professionals should consider the use of alternative treatments to Innohep when treating elderly patients over 70 years of age with renal insufficiency and deep vein thrombosis (DVT), pulmonary embolism (PE), or both.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Deep vein thrombosis (DVT) in the surgical setting

GUIDELINE CATEGORY

Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Preventive Medicine
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide medical practitioners with a current understanding of the principles and strategies for the prevention of deep vein thrombosis in patients undergoing urologic surgery

TARGET POPULATION

All adult patients undergoing urological surgical procedures

Note: Pediatric urologic surgery and renal transplantation were excluded because of the relative paucity of literature concerning these areas.

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Prevention

1. Assessment of patient-specific and procedure-specific risk factors for the development of deep vein thrombosis (DVT) and risk stratification
2. DVT prophylaxis including:
    - Early ambulation

- Graduated compression stockings (GCS) and intermittent pneumatic compression (IPC)
- Pharmacologic agents (low molecular weight heparin [LMWH] or low-dose unfractionated heparin [LDUH])

MAJOR OUTCOMES CONSIDERED

- Incidence of deep vein thrombosis (DVT)
- Incidence of pulmonary thromboembolism
- Thromboembolic complications
- Hemorrhagic complications
- Morbidity
- Mortality
- Intraoperative transfusion rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The initial Medline search was supplemented by review of bibliographies and additional focused searches. In all, 105 articles were deemed by the Panel members to be suitable for scrutiny. From these papers, the Panel identified four categories of urologic surgeries which appeared to be candidates for deep vein thrombosis (DVT) prophylaxis: transurethral surgery, anti-incontinence and pelvic reconstructive surgery, laparoscopic urologic and/or robotically assisted laparoscopic procedures, and open urologic surgery. Pediatric urologic surgery and renal transplantation were excluded because of the relative paucity of literature concerning these areas.

NUMBER OF SOURCE DOCUMENTS

A total of 105 articles were deemed by the Panel members to be suitable for scrutiny.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Assessment of the literature by the American Urological Association Practice Guidelines Committee (AUA PGC) found insufficient outcomes data to support a formal meta-analysis and an evidence-based guideline on the prevention of deep vein thrombosis (DVT) during urological surgery. The evidence was generally of a low level, being derived overwhelmingly from nonrandomized studies. Thus, the Panel was charged with developing a Best Practice Statement, which employs published data in concert with expert opinion. Due to the lack of robust data, an evidence table could not be developed.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The supporting systematic literature review and the drafting of this document were conducted by the Prevention of Deep Vein Thrombosis in Patients Undergoing Urologic Surgery Panel (the Panel) created in 2006 by the American Urological Association (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel chair who in turn appointed the additional Panel members with specific expertise in this disease.

The mission of the Panel was to develop either analysis- or consensus-based recommendations, depending on the type of evidence available and Panel processes, to support optimal clinical practices in the prevention of deep vein thrombosis in patients undergoing urologic surgery. Each Panel member was assigned to assess the evidence relevant to their area of expertise and to draft a section of the document based on their review of the literature and expertise.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was submitted for peer review, and comments from 23 physicians and researchers were considered by the Panel in making revisions. The final

document was approved by the American Urological Association Practice Guidelines Committee (AUA PGC) and the Board of Directors (BOD).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Therapeutic Options for Thromboprophylaxis

Depending on the level of patient risk for thromboembolism, the following therapies can be used alone or in combination as options for the prevention of deep vein thrombosis (DVT) in the surgical setting:

- Mechanical (nonpharmacologic) therapies – early ambulation, graduated compression stockings (GCS), and intermittent pneumatic compression (IPC)
- Pharmacologic agents – low-dose unfractionated heparin (LDUH) and low molecular weight heparin (LMWH)

Defining Risk Levels

Patient-specific predisposing factors increase the risk of DVT in patients undergoing urologic surgery. These factors are wide ranging and include immobility, trauma, malignancy, previous cancer therapy, past history of DVT, increasing age, pregnancy, estrogen therapy, obesity, smoking, and venous varicosities; these as well as additional factors increasing the risk of DVT are listed in Table 1 below.

Table 1: Risk Factors for Increased Development of Deep Vein Thrombosis

Surgery
Trauma (major or lower extremity)
Immobility, paresis
Malignancy
Cancer therapy (hormonal, chemotherapy, or radiotherapy)
Previous Venous Thromboembolism
Increasing age
Pregnancy and the postpartum period
Estrogen-containing oral contraception or hormone replacement therapy
Selective estrogen receptor modulators
Acute medical illness
Heart or respiratory failure
Inflammatory bowel disease
Nephrotic syndrome
Myeloproliferative disorders
Paroxysmal nocturnal hemoglobinuria
Obesity
Smoking
Varicose veins
Central venous catheterization

Inherited or acquired thrombophilia

Adapted with permission from Geerts, W.H., Pineo, G.F., Heit, J.A., et al.: Prevention of venous thromboembolism. Chest 2004; 126: 338S-400S.

When assessing the risk of DVT for an individual patient, both the procedure, with its inherent risk, and the patient's specific, predisposing factors must be considered. The appropriate DVT prophylaxis for a low-risk procedure may be more complex in a patient with a high-risk profile. A risk stratification table has been constructed to provide guidance in choosing the appropriate preventative measures (see Table 2 below).

Table 2: Patient Risk Stratification

Low Risk	Minor* surgery in patients <40 years with no additional risk factors
Moderate Risk	Minor* surgery in patients with additional risk factors Surgery in patients aged 40-60 years with no additional risk factors
High Risk	Surgery in patients >60 years Surgery in patients aged 40-60 years with additional risk factors (prior venous thromboembolism, cancer, hypercoagulable state, see Table 1 in the original guideline document)
Highest Risk	Surgery in patients with multiple risk factors (age >40 years, cancer, prior venous thromboembolism)

* For the purposes of this paper, minor surgery is defined as a procedure with a relatively short operating time in which the patient is rapidly ambulatory. Adapted with permission from Geerts, W.H., Pineo, G.F., Heit, J.A., et al.: Prevention of venous thromboembolism. Chest 2004; 126: 338S-400S.

Transurethral Surgery

For the vast majority of transurethral procedures, early ambulation is recommended for DVT prophylaxis. For patients at increased risk of DVT undergoing transurethral resection of the prostate (TURP), the use of GCS, IPC, postoperative LDUH or LMWH may be indicated.

Anti-Incontinence and Pelvic Reconstructive Surgery

The prevention of DVT in patients undergoing anti-incontinence and pelvic reconstructive surgeries should be dictated by preoperative individual patient risk factors and procedure-specific risk factors for DVT formation.

- For low-risk patients undergoing minor procedures the use of early postoperative ambulation appears to be sufficient.
- For moderate-risk patients undergoing higher risk procedures, the use of IPC, LDUH, or LMWH should be utilized.

- For high-risk and highest-risk patients undergoing higher-risk procedures, combination therapy with IPC plus LDUH or LMWH should be utilized unless the bleeding risk is considered unacceptably high.

Urologic Laparoscopic and/or Robotically Assisted Urologic Laparoscopic Procedures

In view of the lack of large randomized controlled trials (RCTs) addressing this issue as well as the concerns for increased retroperitoneal bleeding at the time of urologic laparoscopic procedures, the Panel recommends the use of IPC devices at the time of the laparoscopic procedure. High-risk groups which may require the use of LDUH and LMWH may be identified.

Open Urologic Surgery

The Panel recommends the use of IPC in patients undergoing open urologic procedures. Given the increased risk factors within this patient population, in many patients undergoing open urologic procedures, more aggressive regimens combining the use of IPC with pharmacologic prophylaxis may be considered.

Venous Thromboembolism (VTE) Prophylaxis Recommendations

Level of Risk	Prophylactic Treatment
Low Risk	No prophylaxis other than early ambulation
Moderate Risk	• Heparin 5000 units every 12 hours subcutaneous starting after surgery • **OR** *Enoxaparin 40 mg (Cr Cl < 30 ml/min = 30 mg) subcutaneous daily • **OR** Pneumatic compression device if risk of bleeding is high
High Risk	• Heparin 5000 units every 8 hours subcutaneous starting after surgery • **OR** *Enoxaparin 40 mg (Cr Cl < 30 ml/min = 30 mg) subcutaneous daily • **OR** Pneumatic compression device if risk of bleeding is high
Very High Risk	• *Enoxaparin 40 mg (Cr Cl < 30 ml/min = 30 mg) subcutaneous daily **and** adjuvant pneumatic compression device, or • Heparin 5000 units every 8 hours subcutaneous starting after surgery **and** adjuvant pneumatic compression device

***Guidelines and Cautions for Enoxaparin Use**

- In patients with a body weight > 150 Kg consider increasing prophylaxis dose of Enoxaparin to 40 mg subcutaneous every 12 hours.
- Withhold Enoxaparin generally for at least 2 to 3 days after major trauma, and then only consider use after review of current patient condition and risk benefit ratio.

- For planned manipulation of an epidural or spinal catheter (insertion, removal), Enoxaparin should be avoided/held for 24 hours BEFORE planned manipulation and should be resumed no earlier than 2 hours FOLLOWING manipulation.
- Special testing may be indicated for Enoxaparin in a patient with a history of heparin-induced thrombocytopenia.
- **The risks of bleeding must be weighed against the benefits of prophylaxis in determining the timing of initiation of DVT pharmacologic prophylaxis in combination with mechanical prophylaxis.**

In selected very high-risk patients, clinicians should consider post-discharge Enoxaparin or Warfarin.

Abbreviations: mg, milligram; Cr Cl, creatinine clearance; ml, milliliter; min, minute; Kg, kilogram

Conclusion

DVT prophylaxis should be considered in all patients undergoing urologic surgical procedures. In many patients undergoing low-risk procedures, early ambulation may be the only DVT prophylactic measure that is indicated. However, in patients with a high-risk profile undergoing a high-risk procedure, an assessment of all risk factors inherent to the patient and planned procedure should dictate the appropriate DVT prophylaxis. Future randomized trials comparing the different pharmacologic interventions would be useful and should be developed; the economics of thromboprophylaxis also should be evaluated.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

The report is based on review of available professional literature as well as clinical experience and expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved prevention of deep vein thrombosis (DVT) in patients undergoing urologic surgery

POTENTIAL HARMS

Adverse Effects of Medications

- *Low molecular weight heparin (LMWH)* is associated with nonfatal or fatal hemorrhage at any site, tissue or organ; thrombocytopenia; elevations of serum aminotransferases; local reactions, including irritation, pain, hematoma, ecchymosis and erythema; hypersensitivity reactions; spinal/epidural hematoma with spinal/epidural anesthesia or spinal puncture. LMWH should be used with extreme caution in patients with:
    - Thrombocytopenia (patients with any degree of thrombocytopenia should be actively monitored)
    - Liver failure with elevated international normalized ratio (INR) (>1.5)
    - Uncontrolled arterial hypertension (systolic >200, diastolic >110)
    - Conditions associated with increased risk of hemorrhage
    - Severe renal impairment
    - Concurrent spinal/epidural anesthesia or spinal puncture
- *Heparin sodium* can cause hemorrhage at any site; thrombocytopenia; elevations of aminotransferases; local reactions, including irritation, erythema, mild pain, hematoma, or ulceration; hypersensitivity reactions. It should be used with extreme caution in patients with:
    - Increased risk of hemorrhage and with concurrent oral anticoagulants and antiplatelet drugs
    - White clot syndrome
    - Increased resistance to heparin with various conditions
    - A higher incidence of bleeding reported in patients (particularly women) over 60 years of age

Refer to Appendix 3 of the original guideline document for details.

CONTRAINDICATIONS

CONTRAINDICATIONS

- *Low molecular weight heparin (LMWH)* should not be used in patients with:
    - Active major bleeding
    - Thrombocytopenia with a positive *in vitro* test for antiplatelet antibody in the presence of the drug [enoxaparin; dalteparin] or history of heparin-induced thrombocytopenia [tinzaparin]
    - Known sensitivity to the agent, heparin, sulfites, benzyl alcohol or pork products
    - Patients aged 90 years or older with creatinine clearance <60 ml/minute [tinzaparin]
- *Heparin sodium* should not be used in patients with:
    - Severe thrombocytopenia
    - Uncontrollable active bleeding state, except when due to disseminated intravascular coagulation
    - An inability to receive appropriate blood coagulation tests (applies only to full-dose heparin, not low-dose heparin)
    - In cases of documented hypersensitivity to heparin, except in clearly life-threatening situations

Refer to Appendix 3 of the original guideline document for details.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document provides guidance only and does not establish a fixed set of rules or define the legal standard of care. As medical knowledge expands and technology advances, this guideline will change. Today they represent not absolute mandates but provisional proposals or recommendations for treatment under the specific conditions described. For all these reasons, this best practice statement does not preempt physician judgment in individual cases. Also, treating physicians must take into account variations in resources, and in patient tolerances, needs and preferences. Conformance with the best practice statement reflected in this document cannot guarantee a successful outcome.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

American Urological Association, Inc. (AUA)

GUIDELINE COMMITTEE

Prevention of Deep Vein Thrombosis in Patients Undergoing Urologic Surgery Best Practice Panel

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Urological Association, Inc. (AUA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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